UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/629,348	07/28/2003	Adam Heller	TS-02-92	6348

30349 7590 05/08/2007

JACKSON & CO., LLP
6114 LA SALLE AVENUE
#507
OAKLAND, CA 94611-2802

EXAMINER	
NOGUEROLA, ALEXANDER STEPHAN	
ART UNIT	**PAPER NUMBER**
1753	

MAIL DATE	DELIVERY MODE
05/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/629,348	HELLER ET AL.	
	Examiner	Art Unit	
	ALEX NOGUEROLA	1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 February 2007 and 28 February 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *45-88* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *45-88* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Applicant's amendment of February 26, 2007 and supplemental amendment of February 28, 2007 do not render the application allowable. Applicant has amended the independent claims to require that the piercing member and the sensor are mechanically attached together to form an integrated unit. In the Examiner's view, as discussed in the new rejections below, this limitation is already taught by Figures 1-3 of Nakashima and with regard to the rejections based on Diebold, this new limitation is rendered obvious by Schindele (US 5,025,798) and the JPO abstract and Figure 4 of Miyawaki et al. (JP 59147249 A) ("Miyawaki »).

Status of the Rejections pending since the Office action of October 05, 2006

2. All previous rejections are withdrawn because of Applicant's amendment to all of the independent claims. However, the rejections of the limitations in the dependent claims are the same (although the rejections of the underlying base claims have

changed) and are presented below for Applicant's convenience, except for the double patenting rejections based on US 6,607,658 B1, which have been overcome by a terminal disclaimer.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Double Patenting rejections based on U.S. Patent No. 6,120,676 B1

4. Claims 45, 46, 62, 70, and 71 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 101 of U.S. Patent No. 6,120,676 B1 in view of newly citeed Schindele (US 5,025,798) and the JPO abstract and Figure 4 of Miyawaki et al. (JP 59147249 A) ("Miyawaki »). Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of claim 101 of U.S. Patent No. 6,120,676 B1 uses a device that has the features claimed in claims 45, 46, 62, and 70 of the instant application except for requiring the piercing member and the sensor to be mechanically attached to form an integrated unit. However, to make parts integral is, per se, not inventive. As shown by Schindele and Miyawaki, for example, it was known at the time of the invention to make a lancet integral with hand-held sensing device. As shown by Figure 4 of Schindele a cylinder with a fixed lancet at one end can be fitted at its other end over the front end of the sensor and so made integral with the sensor. As shown by the embodiment of Figure 4 of Miyawaki with a suitable cylindrical support structure (17) a lancet can be fixed to the sensor. It would have been obvious to one with ordinary skill in the art to make the piercing member integral with the device as taught by Schindele or Miyawaki in the invention of claim 101 of U.S. Patent No. 6,120,676 B1 because the patient will then be able to more easily and conveniently make his measurements as he will not have to handle and align different pieces of equipment.

5. Claims 47-49 and 72-74 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the combination of claims 107, 67, and 50 of U.S. Patent No. 6,120,676 B1 Schindele (US 5,025,798) and the JPO abstract and Figure 4 of Miyawaki et al. (JP 59147249 A) ("Miyawaki »). Claim 45, from which claim 47 depends, and claim 70, from which claim 72 depends, have been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because the related method claims 107, 67, and 50 meet the additional limitations of claims 47-49 and 72-74.

6. Claims 50 and 75 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 104 of U.S. Patent No. 6,120,676 B1 Schindele (US 5,025,798) and the JPO abstract and Figure 4 of Miyawaki et al. (JP 59147249 A) ("Miyawaki »). Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of claim 104 of U.S. Patent No. 6,120,676 B1 uses a device that has the features claimed in claims 50 and 75 of the instant application.

7. Claims 52 and 76 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the combination of claims 28 and 101 of U.S. Patent No. 6,120,676 B1 Schindele (US 5,025,798) and the JPO abstract and Figure 4 of Miyawaki et al. (JP 59147249 A) ("Miyawaki »). Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of claims 28 and 101 of U.S. Patent No. 6,120,676 B1 uses a device that has the features claimed in claims 52 and 76 of the instant application.

8. Claims 54 and 77 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the combination of claims 30 and 101 of U.S. Patent No. 6,120,676 B1 Schindele (US 5,025,798) and the JPO abstract and Figure 4 of Miyawaki et al. (JP 59147249 A) ("Miyawaki »). Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of claims 30 and 101 of U.S. Patent No. 6,120,676 B1 uses a device that has the features claimed in claims 54 and 77 of the instant application.

9. Claims 56-58, 60, 79, 80, 81, and 82 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the combination of claims 107 and 85 of U.S. Patent No. 6,120,676 B1 Schindele (US 5,025,798) and the

JPO abstract and Figure 4 of Miyawaki et al. (JP 59147249 A) ("Miyawaki »). Claim 45, from which claims 56 and 58 depend, and claim 70, from which claims 79, 81, and 82 depends, have been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because the related method claims 107 and 85 meet the additional limitations of claims 56-58 and 60.

10. Claims 63, 64, 85, and 86 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the combination of claims 101 and 11 of U.S. Patent No. 6,120,676 B1 Schindele (US 5,025,798) and the JPO abstract and Figure 4 of Miyawaki et al. (JP 59147249 A) ("Miyawaki »). Claim 45, from which claims 63 and 64 depend, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because the related method claims 101 and 11 meet the additional limitations of claims 63, 64, 85, and 86.

Double Patenting rejections based on U.S. Patent No. 6,551,494 B1

11. Claims 45, 62, and 70 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,551,494 B1 in view of Schindele (US 5,025,798) and the JPO abstract and Figure 4 of Miyawaki et al. (JP 59147249 A) ("Miyawaki »). Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of claim 1 of U.S. Patent No. 6,551,494 B1 uses a device that has the features claimed in claims 45, 62, and 70 of the instant application for coulometry except for requiring the piercing member and the sensor to be mechanically attached to form an integrated unit. However, to make parts integral is, per se, not inventive. As shown by Schindele and Miyawaki, for example, it was known at the time of the invention to make a lancet integral with hand-held sensing device. As shown by Figure 4 of Schindele a cylinder with a fixed lancet at one end can be fitted at its other end over the front end of the sensor and so made integral with the sensor. As shown by the embodiment of Figure 4 of Miyawaki with a suitable cylindrical support structure (17) a lancet can be fixed to the sensor. It would have been obvious to one with ordinary skill in the art to make the piercing member integral with the device as taught by Schindele or Miyawaki in the invention of claim 1 of U.S. Patent No. 6,551,494 B1 because the patient will then be able to more easily and conveniently make his measurements as he will not have to handle and align different pieces of equipment.

12. Claims 47-49 and 72-74 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the combination of claims 10 and 6 of U.S. Patent No. 6,551,494 B1 in view of Schindele (US 5,025,798) and the JPO abstract and Figure 4 of Miyawaki et al. (JP 59147249 A) ("Miyawaki »). Claim 45, from which claim 47 depends, and claim 70, from which claim 72 depends, have been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because the related method claims 10 and 6 meet the additional limitations of claims 47-49 and 72-74.

13. Claims 50 and 75 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 12 of U.S. Patent No. 6,551,494 B1 in view of Schindele (US 5,025,798) and the JPO abstract and Figure 4 of Miyawaki et al. (JP 59147249 A) ("Miyawaki »). Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of claim 12 of U.S. Patent No. 6,551,494 B1 uses a device that has the features claimed in claims 50 and 75 of the instant application.

14. Claims 52 and 76 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 4 of U.S. Patent No. 6,551,494 B1 in

view of Schindele (US 5,025,798) and the JPO abstract and Figure 4 of Miyawaki et al. (JP 59147249 A) ("Miyawaki »). Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of claim 4 of U.S. Patent No. 6,551,494 B1 uses a device that has the features claimed in claims 52 and 76 of the instant application.

15. Claims 54 and 77 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the combination of claims 10 and 16 of U.S. Patent No. 6,551,494 B1 in view of Schindele (US 5,025,798) and the JPO abstract and Figure 4 of Miyawaki et al. (JP 59147249 A) ("Miyawaki »). Claim 45, from which claim 54 depends, and claim 70, from which claim 77 depends, have been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because the related method claims 10 and 16 meet the additional limitations of claims 54 and 77.

16. Claims 56-58, 60, 79, and 80 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the combination of claims 1 and 26 of U.S. Patent No. 6,551,494 B1 in view of Schindele (US 5,025,798) and the JPO abstract and Figure 4 of Miyawaki et al. (JP 59147249 A) ("Miyawaki »).

Claim 45, from which claims 56, 58, and 60 depend, and claim 70, from which claim 79 depends, have been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because the related method claims 1 and 26 meet the additional limitations of claims 56, 58, and 60.

17. Claims 59 and 81 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the combination of claims 1 and 28 of U.S. Patent No. 6,551,494 B1 in view of Schindele (US 5,025,798) and the JPO abstract and Figure 4 of Miyawaki et al. (JP 59147249 A) ("Miyawaki »). Claim 58, from which claims 59 depends, and claim 70, from which claim 82 depends, have been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because the related method claims 1 and 28 meet the additional limitations of claim 59.

18. Claims 61 and 83 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the combination of claims 1 and 32 of U.S. Patent No. 6,551,494 B1 in view of Schindele (US 5,025,798) and the JPO abstract and Figure 4 of Miyawaki et al. (JP 59147249 A) ("Miyawaki »). Claim 45, from which claim

61 depends, and claim 70, from which claim 83 depends, have been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because the related method claims 1 and 32 meet the additional limitations of claims 61 and 83.

19. Claims 63, 64, 85, and 86 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the combination of claims 14 and 1 of U.S. Patent No. 6,551,494 B1 in view of Schindele (US 5,025,798) and the JPO abstract and Figure 4 of Miyawaki et al. (JP 59147249 A) ("Miyawaki »). Claim 45, from which claims 63 and 64 depend, and claim 70, from which claims 85 and 86 depend, have been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because the related method claims 14 and 1 meet the additional limitations of claims 63, 64, 85, and 86.

Claim Rejections - 35 USC § 103

20. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

21. Claims 45, 46, 50, 51, 53-55, 61, 63-71, 75, 77, 78, 83, and 85-88 are rejected under 35 U.S.C. 103(a) as being unpatentable over the English language translation of Nakashima et al. (JP 02-326247) ("Nakashima") in view of Asa et al. (US 4,917,274) ("Asa") and Bratten et al. ("Micromachining sensors for Electrochemical Measurement in Subnanoliter Volumes," Analytical Chemistry, vol. 69, No. 2, January 15, 1997) ("Bratten").

Addressing claims 45 and 70, Nakashima discloses a device for determining the concentration of an analyte in a biological fluid from a patient (bottom paragraph on page 2), comprising

a piercing member (3) sufficient to cause the fluid to flow from a site on the patient (first full paragraph on page 5);

a sensor (4) sufficient to generate an electrical signal indicative of the concentration of the analyte in the fluid (page 7, bottom paragraph to page 8, second full paragraph after the formula at the top of the page), the sensor comprising: a working electrode (42); a sensing layer (45b); a counter electrode (43); and a measurement zone (inside of cap 2); and

an analyzer (1) operatively connected to the sensor (Figures 1 and 3), and

wherein the piercing member and the sensor are mechanically attached together to form an integrated unit (as seen form Figure 3 and discussed at the bottom of page 5 of Nakashima the piercing member (3) is mechanically attached to the main body (1) by connector (14). As seen in Figure 2 the cap body (2), which contains the sensor (4), is mechanically attached to the main body by a snap-fit comprising an inner

circumferential groove on the main body into which an outer circumferential protrusion on the cap rests and an outer circumferential groove on the cap into which an inner circumferential protrusion on the main body rests. Thus the piercing member and the sensor are mechanically attached via this snap-fit arraignment that secures the cap to the main body. Such a mechanical attachment is no different in principle (and by the broad language of this new limitation) from the way the piercing member and the sensor are attached in Applicant's Figure 6, which shows the piercing member attached to sensor (measurement region) via attachment to the main body of the sensor.)

Nakashima does not mention whether the measurement zone is sized to contain a volume of less than about 1 µl. As a first matter even if the measurement zone of Nakashima is greater than 1 µl then it will still be sized to contain a volume of less than about 1 µl since any volume greater than 1 µl can contain a volume smaller than 1 µl. In any event, barring evidence to the contrary, such as unexpected results, having the measurement zone be sized to contain a volume of less than about 1 µl is just a matter of scaling the measurement zone for the expected range of sample volumes. Nakashima clearly already contemplates a very small sample size as the device is intended for use with only a blood droplet (third full paragraph on page 3). Also, as shown by Bratten it was known at the time of the invention how to manufacture a working electrode, counter electrode, and pseudoreference electrode on a substrate located in a microchamber of only 0.6 nl (abstract) and shown by Asa it was known at the time of the invention how to manufacture a submicron pipette tip (abstract and col. 02:50-53), which the sensor of Nakashima is located in (third full paragraph on

page 6). Thus, there was no manufacturing hurdle. By making the measurement zone smaller there will be less pain and inconvenience to the patient while acquiring the sample.

For claim 70, note that the claimed method steps are just using the above described sensor as intended and are in fact either implied or necessary steps. See, for example, page 2 and the bottom page of page 7 to the second full paragraph on page 8 of Nakashima.

Addressing clams 46 and 71, for the additional limitations of these claims see in Nakashima the second full paragraph on page 6.

Addressing claims 50 and 75, for the additional limitations of these claims note that as in the rejection of claim 45 barring evidence to the contrary, such as unexpected results, having the measurement zone be sized to contain a volume of less than about 0.5 µl is just a matter of scaling the measurement zone for the expected range of sample volumes.

Addressing clams 51 and 53, for the additional limitations of these claims see in Nakashima Figure 2.

Addressing claims 54 and 77, Nakashima does not mention providing a reference electrode. Bratten teaches providing a reference electrode in a subnanoliter measurement zone in Figure 2. It would have been obvious to one with ordinary skill in the art at the time the invention was made to provide a reference electrode as taught by Bratten in the invention of Nakashima because it was known in the art at the time of invention to provide a separate reference electrode in addition to a counter electrode to improve the accuracy of the measurement. If there is a separate reference electrode spurious current will go through the counter electrode instead of the reference electrode, thus helping to stabilize the reference electrode.

Addressing Claims 55 and 78, Nakashima as modified by Asa and Bratten does not mention whether the sensor has the claimed property; however, since the sensor of Nakashima as modified by Asa and Bratten is structurally the same as that of underlying claim 45 it should have the same properties as the claimed sensor.

Addressing claims 61 and 83, an amperometric technique for determining the concentration is implied in the first paragraph on page 8 of Nakashima, which teaches measuring current that is proportional to concentration of analyte.

Addressing claims 63, 64, 85, and 86, for the additional limitations of these claims see in Nakashima the bottom paragraph on page 7 and the top of page 8.

Addressing clams 65, 66, and 88, for the additional limitations of these claims see in Nakashima Figures 1-3.

22. Addressing claims 67, and 68, Nakashima discloses a device for determining the concentration of an analyte in a biological fluid from a patient (bottom paragraph on page 2), comprising

a piercing member (3) sufficient to cause the fluid to flow from a site on the patient (first full paragraph on page 5); and

a sensor (4) sufficient to generate an electrical signal indicative of the concentration of the analyte in the fluid (page 7, bottom paragraph to page 8, second full paragraph after the formula at the top of the page), the sensor comprising: a working electrode (42); a sensing layer (45b); a counter electrode (43); and a measurement zone (inside of cap 2), and

wherein the piercing member and the sensor are mechanically attached together to form an integrated unit (as seen form Figure 3 and discussed at the bottom of page 5 of Nakashima the piercing member (3) is mechanically attached to the main body (1) by connector (14). As seen in Figure 2 the cap body (2), which contains the sensor (4), is

mechanically attached to the main body by a snap-fit comprising an inner circumferential groove on the main body into which a outer circumferential protrusion on the cap rests and an outer circumferential groove on the cap into which an inner circumferential protrusion on the main body rests. Thus the piercing member and the sensor are mechanically attached via this snap-fit arraignment that secures the cap to the main body. Such a mechanical attachment is no different in principle (and by the broad language of this new limitation) from the way the piercing member and the sensor are attached in Applicant's Figure 6, which shows the piercing member attached to sensor (measurement region) via attachment to the main body of the sensor.)

Nakashima does not mention whether the measurement zone is sized to contain a volume of less than about 1 µl. As a first matter even if the measurement zone of Nakashima is greater than 1 µl then it will still be sized to contain a volume of less than about 1 µl since any volume greater than 1 µl can contain a volume smaller than 1 µl. In any event, barring evidence to the contrary, such as unexpected results, having the measurement zone be sized to contain a volume of less than about 1 µl is just a matter of scaling the measurement zone for the expected range of sample volumes. Nakashima clearly already contemplates a very small sample size as the device is intended for use with only a blood droplet (third full paragraph on page 3). Also, as shown by Bratten it was known at the time of the invention how to manufacture a working electrode, counter electrode, and pseudoreference electrode on a substrate located in a microchamber of only 0.6 nl (abstract) and shown by Asa it was known at the time of the invention how to manufacture a submicron pipette tip (abstract and

col. 02:50-53), which the sensor of Nakashima is located in (third full paragraph on page 6). Thus, there was no manufacturing hurdle. By making the measurement zone smaller there will be less pain and inconvenience to the patient while acquiring the sample.

Nakashima as modified by Asa and Bratten does not mention whether the sensor has the claimed property of signal generation; however, since the sensor of Nakashima as modified by Asa and Bratten is structurally the same as that of underlying claim 45 it should have the same properties as the claimed sensor.

Addressing claim 69, for the additional limitation of this claim note element 1 in Figures 1 and 3 of Nakashima.

Addressing Claim 87, Nakashima et al. as modified by Bratten and Asa only disclose causing blood to flow from a finger tip. However, barring evidence to the contrary, such as unexpected results, the location from which blood will be caused to flow, such as from a site on an arm, will depend on whether it is most the accessible site and piercing the skin there will cause the least pain.

23. Claims 47-49 and 72-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over the English language translation of Nakashima et al. (JP 02-326247) ("Nakashima") in view of Asa et al. (US 4,917,274) ("Asa") and Bratten et al. ("Micromachining sensors for Electrochemical Measurement in Subnanoliter Volumes," Analytical Chemistry, vol. 69, No. 2, January 15, 1997) ("Bratten") as applied to claims 45, 46, 50, 51, 53-55, 61, 63-71, 75, 77, 78, 83, and 85-88 above, and further in view of Diebold et al. (US 5,437,999) ("Diebold").

Addressing claims 47-49, Nakashima discloses glucose oxidase as an enzyme and oxygen as a mediator. See the bottom of page 7 and the top of page 8.

Diebold discloses a device for determining the concentration of an analyte in a biological fluid from a patient (abstract and col. 10:35-40), comprising

a piercing member sufficient to cause the fluid to flow from a site on the patient (col. 12:35-39);

a sensor (Figure 6) sufficient to generate an electrical signal indicative of the concentration of the analyte in the fluid (col. 12:35-42), the sensor comprising: a working electrode (11); a sensing layer (col. 12:56-62); a counter electrode (48); and a measurement zone (49); and

an analyzer operatively connected to the sensor (col. 13:9-13).

Diebold further discloses that other mediators, such as ferricyande and imidazole osmium, were known at the time of the invention. See col. 12:18-32. Barring evidence to the contrary, such as unexpected result, the choice of mediator is just a

matter of optimizing the reaction layer. Another mediator than oxygen may be used in Nakashima, for example, if an oxygen deficiency is likely near the measurement area.

24. Claims 62 and 84 are rejected under 35 U.S.C. 103(a) as being unpatentable over the English language translation of Nakashima et al. (JP 02-326247) ("Nakashima") in view of Asa et al. (US 4,917,274) ("Asa") and Bratten et al. ("Micromachining sensors for Electrochemical Measurement in Subnanoliter Volumes," Analytical Chemistry, vol. 69, No. 2, January 15, 1997) ("Bratten") as applied to claims 45, 46, 50, 51, 53-55, 61, 63-71, 75, 77, 78, 83, and 85-88 above, and further in view of Wojciechowski et al. (US 5,873,990), hereafter "Wojciechowski."

Nakashima as modified by Asa and Bratten does not mention using a coulometric technique; however, coulometry was one of several electrochemical analytical techniques used at the time of the invention for measuring analyte in blood. See in Wojciechowski the abstract; column 2, lines 20-27; and col. 2, ll. 40-52. Barring evidence to the contrary, such as unexpected results, since it was known to use coulometry and other electrochemical techniques to analyze blood, selecting the electrochemical technique to be used, such as coulometry, is just a matter of choosing the best technique for the analyte, sample, and information desired, whether concentration or just determination of presence.

25. Claims 45-55, 61, 63-65, 67-78, 83, and 85-88 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diebold et al. (US 5,437,999) ("Diebold") in view of newly cited Schindele (US 5,025,798) and the JPO abstract and Figure 4 of Miyawaki et al. (JP 59147249 A) ("Miyawaki »), and Straus et al. (US 5,089,320) ("Straus").

Addressing claims 45, 65, 70, and 88, Diebold discloses a device for determining the concentration of an analyte in a biological fluid from a patient (abstract and col. 10:35-40), comprising

a piercing member sufficient to cause the fluid to flow from a site on the patient (col. 12:35-39);

a sensor (Figure 6) sufficient to generate an electrical signal indicative of the concentration of the analyte in the fluid (col. 12:35-42), the sensor comprising: a working electrode (11); a sensing layer (col. 12:56-62); a counter electrode (48); and a measurement zone (49); and

an analyzer operatively connected to the sensor (col. 13:9-13).

Although the Examiner believes that the disclosed piercing member (lancet) is part of the device, assuming that it can be shown that it is not, in any event to make parts integral is not inventive. As shown by Schindele and Miyawaki, for example, it was known at the time of the invention to make a lancet integral with hand-held sensing device. As shown by Figure 4 of Schindele a cylinder with a fixed lancet at one end can be fitted at its other end over the front end of the sensor and so made integral with the sensor. As shown by the embodiment of Figure 4 of Miyawaki with a suitable cylindrical support structure (17) a lancet can be fixed to the sensor. It would have been

obvious to one with ordinary skill in the art to make the piercing member integral with the device as taught by Schindele or Miyawaki in the invention of Diebold because the patient will then be able to more easily and conveniently make his measurements as he will not have to handle and align different pieces of equipment.

As for the measurement zone being sized to contain a volume of less than about 1 µl. As a first matter even if the measurement zone of Diebold is greater than 1 µl then it will still be sized to contain a volume of less than about 1 µl since any volume greater than 1 µl can contain a volume smaller than 1 µl. In any event, barring evidence to the contrary, such as unexpected results, having the measurement zone be sized to contain a volume of less than about 1 µl is just a matter of scaling the measurement zone for the expected range of sample volumes. Diebold is directed to a small volume sensor and discloses a cell volume of 3 microns. See the abstract and col. 12:35-42. The spacer, by its thickness, and the width of the capillary channel, together define the cell volume in Diebold. See Figure 5. The spacer may be made of a plastic film, such as MYLAR™ film. See Figure 5 and col. 7:14-18 and col. 7:55-57. As shown by Straus, at the time of the invention MYLAR™ film of only 12.2 microns in thickness was commercially available. See col. 4:53-56. Diebold also discloses using a laser to from a cutout that defines the capillary channel. See col. 7:14-21. Thus, barring evidence to the contrary, such as unexpected results, having an effective cell volume of less than 1.0 microliters is just a matter of scaling the cell volume in Diebold by using a thin enough spacer, such as using the 12.2 micron thick Dupont Mylar film disclosed by

Straus, and/or creating a narrow enough capillary channel by using a thin enough laser beam.

For claim 70, not that the claimed method steps are just using the above described sensor as intended and are in fact either implied or necessary steps. See, for example, col. 12:63 – col. 13:26 of Diebold.

Addressing claims 46 and 71, for the additional limitations of these claims see in Diebold col. 12:35-42 and in Smith col. 21:41 – col. 22:49,

Addressing claims 47-49 and 72-74, for the additional limitation of this claim see in Diebold col. 10:35-52.

Addressing claims 50 and 75, for the additional limitation of this claim note that as in the rejection of claim 45 barring evidence to the contrary, such as unexpected results, having the measurement zone be sized to contain a volume of less than about 0.5 µl is just a matter of scaling the measurement zone for the expected range of sample volumes.

Addressing claim 51, for the additional limitation of this claim see in Diebold Figure 6.

Addressing claims 52 and 76, for the additional limitations of these claims see in Diebold Figures 5 and 6.

Addressing claim 53, for the additional limitation of this claim see in Diebold Figure 8b.

Addressing claims 54 and 77, for the additional limitation of this claim see in Diebold col. 05:56-59. It would have been obvious to one with ordinary skill in the art at the time the invention was made to provide a reference electrode because it was known in the art at the time of invention to provide a separate reference electrode in addition to a counter electrode to improve the accuracy of the measurement. If there is a separate reference electrode spurious current will go through the counter electrode instead of the reference electrode, thus helping to stabilize the reference electrode.

Addressing claims 55 and 78, Diebold as modified by Schindele, Miyawaki, and Straus does not mention whether the sensor has the claimed property; however, since the sensor of Bratten as modified by Schindele, Miyawaki, and Straus is structurally the same as that of underlying claim 45 it should have the same properties as the claimed

sensor, especially since Figure 9 of Diebold shows that the sensor of Diebold is very accurate.

Addressing claims 61 and 83, for the additional limitation of this claim see in Diebold col. 13:9-16.

Addressing claims 63, 64, 85, and 86 for the additional limitation of this claim see in Diebold col. 13:6-9.

Addressing claims 67 and 68, Diebold discloses a device for determining the concentration of an analyte in a biological fluid from a patient (abstract and col. 10:35-40), comprising

a piercing member sufficient to cause the fluid to flow from a site on the patient (col. 12:35-39); and

a sensor (Figure 6) sufficient to generate an electrical signal indicative of the concentration of the analyte in the fluid (col. 12:35-42), the sensor comprising: a working electrode (11); a sensing layer (col. 12:56-62); a counter electrode (48); and a measurement zone (49).

Although the Examiner believes that the disclosed piercing member (lancet) is part of the device, assuming that it can be shown that it is not, in any event to make parts integral is not inventive. As shown by Schindele and Miyawaki, for example, it

was known at the time of the invention to make a lancet integral with hand-held sensing device. As shown by Figure 4 of Schindele a cylinder with a fixed lancet at one end can be fitted at its other end over the front end of the sensor and so made integral with the sensor. As shown by the embodiment of Figure 4 of Miyawaki with a suitable cylindrical support structure (17) a lancet can be fixed to the sensor. It would have been obvious to one with ordinary skill in the art to make the piercing member integral with the device as taught by Schindele or Miyawaki in the invention of Diebold because the patient will then be able to more easily and conveniently make his measurements as he will not have to handle and align different pieces of equipment.

As for the measurement zone being sized to contain a volume of less than about 1 µl. As a first matter even if the measurement zone of Nakashima is greater than 1 µl then it will still be sized to contain a volume of less than about 1 µl since any volume greater than 1 µl can contain a volume smaller than 1 µl. In any event, barring evidence to the contrary, such as unexpected results, having the measurement zone be sized to contain a volume of less than about 1 µl is just a matter of scaling the measurement zone for the expected range of sample volumes. Diebold is directed to a small volume sensor and discloses a cell volume of 3 microns. See the abstract and col. 12:35-42. The spacer, by its thickness, and the width of the capillary channel, together define the cell volume in Diebold. See Figure 5. The spacer may be made of a plastic film, such as MYLAR™ film. See Figure 5 and col. 7:14-18 and col. 7:55-57. As shown by Straus, at the time of the invention MYLAR™ film of only 12.2 microns in thickness was commercially available. See col. 4:53-56. Diebold also discloses using a laser to from

a cutout that defines the capillary channel. See col. 7:14-21. Thus, barring evidence to the contrary, such as unexpected results, having an effective cell volume of less than 1.0 microliters is just a matter of scaling the cell volume in Diebold by using a thin enough spacer, such as using the 12.2 micron thick Dupont Mylar film disclosed by Straus, and/or creating a narrow enough capillary channel by using a thin enough laser beam.

Diebold as modified by Schindele, Miyawaki, and Straus does not mention whether the sensor has the claimed property of signal generation; however, since the sensor of Bratten as modified by Schindele, Miyawaki, and Straus is structurally the same as that of underlying claim 45 it should have the same properties as the claimed sensor, especially since Figure 9 of Diebold shows that the sensor of Diebold is very accurate.

Addressing claim 69, for the additional limitation of this claim see in Diebold col. 13:09-13.

Addressing Claim 87, Diebold as modified by Schindele, Miyawaki, and Straus only disclose causing blood to flow from a finger tip. However, barring evidence to the contrary, such as unexpected results, the location from which blood will be caused to flow, such as from a site on an arm, will depend on whether it is most the accessible site and piercing the skin there will cause the least pain.

26. Claims 56-58, 60, 79, 80, and 82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diebold et al. (US 5,437,999), hereafter "Diebold", in view of Schindele (US 5,025,798) and the JPO abstract and Figure 4 of Miyawaki et al. (JP 59147249 A) ("Miyawaki »), Straus et al. (US 5,089,320) ("Straus") as applied to claims 45-55, 61, 63-65, 67-78, 83, and 85-88 above, and further in view of Anderson et al. (US 5,279,294), hereafter "Anderson." Diebold as modified by Smith and Straus does not teach providing a sorbent material (wick), although Diebold does teach providing surfactant to draw sample through the capillary space to the measurement region. See col. 8, ll. 48-52. Anderson teaches a portable electrochemical sensor having a wick. See the abstract; col. 4, ll. 56-59; and col. 2, ll. 29-36. It would have been obvious to one with ordinary skill in the art at the time the invention was made to provide a wick as taught by Anderson in the invention of Diebold as modified by Smith and Straus because as taught by Anderson the wick will transport the sample to the measuring region. See col. 2, ll. 29-36. Unlike a surfactant, the wick will not change the composition of the sample, which may adversely affect the measurements.

27. Claims 62 and 84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schindele (US 5,025,798) and the JPO abstract and Figure 4 of Miyawaki et al. (JP 59147249 A) ("Miyawaki »), Straus et al. (US 5,089,320) ("Straus") as applied to claims 45-55, 61, 63-65, 67-78, 83, and 85-88 above, and further in view of Wojciechowski et al. (US 5,873,990), hereafter "Wojciechowski."

Diebold as modified by Smith and Straus does not mention using a coulometric technique; however, coulometry was one of several electrochemical analytical techniques used at the time of the invention for measuring analyte in blood. See in Wojciechowski the abstract; column 2, lines 20-27; and col. 2, ll. 40-52. Barring evidence to the contrary, such as unexpected results, since it was known to use coulometry and other electrochemical techniques to analyze blood, the electrochemical technique used, such as coulometry, is just a matter of choosing the best technique for the analyte, sample, and information desired, whether concentration or just determination of presence.

Final Rejection

28. Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

1. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Alex Noguerola
Primary Examiner
AU 1753
May 2, 2007